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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,499

08/03/2006

Christopher John Burns

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MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER

WILLIS, DOUGLAS M

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

03/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,499	Applicant(s) BURNS ET AL.	
	Examiner DOUGLAS M. WILLIS	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 and 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

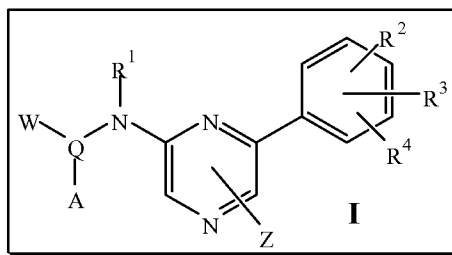
Claims 1-13 and 15-17 are pending in the current application. According to the *Amendments to the Claims*, filed December 29, 2009, claims 1-9 were amended and claim 14 was cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/AU2003/001661, filed December 11, 2003, which claims priority under 35 U.S.C. § 119(e) to US Provisional Application No. 60/483,399, filed June 26, 2003, and under 35 U.S.C. § 119(a-d) to AU 2002953255, filed December 11, 2002.

Status of Priority Objection - Priority Date

Applicant's arguments, on page 10 of the *Remarks*, filed December 29, 2009, with respect to: a) US Provisional Application No. 60/483,399, filed June 26, 2003, and b) AU 2002953255, filed December 11, 2002, have been fully considered, and are persuasive. Consequently, the objection to the priority dates accorded US Provisional Application No. 60/483,399 and AU 2002953255, made in the *Non-Final Rejection*, mailed on October 15, 2009, is hereby withdrawn.

Status of Restrictions / Election of Species

Applicant's affirmation of the following election, without traverse, in the reply filed on December 29, 2009, is acknowledged: a) Group I - claims 1-10; and b) substituted pyrazine of formula I - p. 57, Table 1, example 8.



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The requirement was made FINAL in the *Non-Final Rejection*, mailed on October 15, 2009.

This application contains claims 11-13 and 15-17, drawn to nonelected inventions, without traverse, in the reply filed on December 29, 2009. A complete reply to the final rejection may include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.02.

The sections of U.S.C. Title 35 that formed the basis of prior rejections formulated, as well as any references supporting said rejections, that are not included with this Office action, may be found in the *Non-Final Rejection*, mailed October 15, 2009. Furthermore, any rejections and/or objections of record not explicitly addressed herein below, are hereby withdrawn, in light of applicant's arguments and/or the *Amendments to the Claims*, filed December 29, 2009.

Thus, a second Office action and prosecution on the merits of claims 1-10 is contained within.

Status of Claim Rejections - Obviousness-type Double Patenting

US Application No. 11/367,248

Applicant's arguments, on page 14 of the *Remarks*, filed December 29, 2009, with respect to claims 1-3 and 10, have been fully considered, but are not persuasive. Consequently, the rejection of claims 1-3 and 10, made in the *Non-Final Rejection*, mailed on October 15, 2009, is hereby maintained for the reasons of record.

Applicant primarily argues that the copending application has been abandoned.

In response to applicant's arguments that the copending application has been abandoned, the examiner respectfully disagrees, since the reference application is still copending.

New Claim Objections

Claim 9 is objected to because of the following informalities: the claim is dependent upon a rejected base claim. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Substituted pyrazines of the formula I

Claim 1, 3-8 and 10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, substituted pyrazines of the formula I, where *Q and W are both absent*, lacks adequate support within the specification, as filed. The specification, on page 5, discloses generic substituted pyrazines of the formula I, which fail to expressly include substituted pyrazines where *Q and W are both absent*. Consequently, one of ordinary skill in the art, at the time this application was filed, may neither be reasonably apprised of the scope of the instantly recited substituted pyrazines of the formula I, nor recognize that the inventor was in possession of the instantly recited substituted pyrazines of the formula I, in view of the original disclosure of the application.

Applicant should note that under 35 U.S.C. § 132 and § 251, the proscription against the

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introduction of new matter in a patent application serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. {See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981); and MPEP § 2163.06-2183.07}.

Moreover, applicant should further note that in order to comply with the written description requirement of 35 U.S.C. § 112, first paragraph, each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim *is not present in the written description whose benefit is sought, it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.* {See *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998); and *In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989)}. Consequently, new or amended claims, which introduce elements or limitations which are not supported by the as-filed disclosure, violate the written description requirement. {See *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); and *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972)}. Furthermore, when filing an amendment, applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06.

The examiner suggests removing the limitation *Q and W are both absent*, to overcome this rejection.

New Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

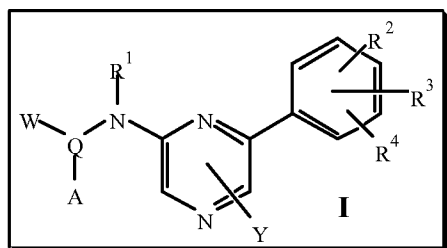
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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

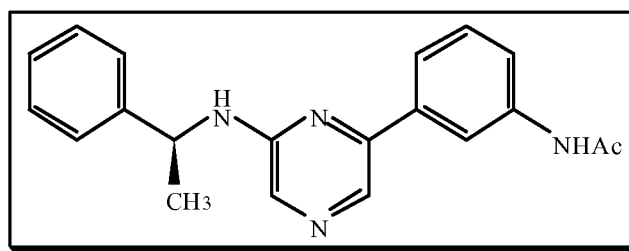
Claims 1, 3-8 and 10 are rejected under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e) as being anticipated by Burns, et al. in WO 02/060492.

The instant application recites substituted pyrazines and pharmaceutical compositions of



the formula I, shown to the left, where $R^1 = -H$; $R^2 = -NR^8COR^9$, wherein $R^8 = -H$ and $R^9 = -C_{1-4}alkyl$; $R^3 = -H$; $R^4 = -H$; $Y = -H$; $Q = -C_{1-4}alkyl$; $W = -C_{1-4}alkyl$; and $A = -aryl$, as tubulin inhibitors.

Burns, et al. (WO 02/060492), as provided in the file and cited on the IDS, teaches substituted pyrazines and pharmaceutical compositions of the formula I, shown to the right, where $R^1 = -H$; $R^2 = -NR^8COR^9$, wherein $R^8 = -H$ and $R^9 = -CH_3$; $R^3 = -H$; $R^4 = -H$; $Y = -H$; $Q = -CH_2-$; $W = -CH_3$; and $A = -Ph$, as protein kinase inhibitors [p. 38, Table 4, compound 20508; and pharmaceutical compositions - p. 17, lines 12-21].



Finally, although not explicitly discussed herein, applicant is advised to note that the Burns reference contains additional species that may anticipate the instantly recited substituted pyrazines of the formula I. Consequently, any amendments to the claims to overcome rejections rendered under 35 U.S.C. § 102 should address this reference as a whole and should not be

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limited to the species discussed or disclosed explicitly herein.

Allowable Subject Matter

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for

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the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/
Examiner, Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, AU 1624**